

REMARKS

By way of the present response, claims 1-9, 11-14, and 20-25 are pending. Claims 2, 5, and 14 have been amended without prejudice or disclaimer to correct minor typographical errors. However, such amendments do not narrow the scope of the claims in any regard. No new matter enters by way of the present amendment. Entry of the amendment and reconsideration of the application based on the following remarks is respectfully requested.

I. Claim Rejections - 35 U.S.C. § 103(a)

Claims 1-8, 13-14 and 20-23 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over WO 03/039597 (Reference 10 from IDS dated 10/30/06 to QLT, Inc., hereinafter, “QLT”) in view of Kalka *et al.* (J Am Acad Dermatol. 389-413, Mar. 2000, hereinafter “Kalka”) and US Published Application 2004/0228885 to Khaiat *et al.* (hereinafter “Khaiat”). This rejection is respectfully traversed for at least the reasons which follow.

The present claims relate to methods of treating acne vulgaris in a subject in need thereof, wherein the claimed methodology is repeated until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment. The cited prior art does not teach or suggest performing methods so as to achieve any stated degree of efficacy of treatment.

As acknowledged by the Examiner, QLT “is silent with regard to the reduction of percentage of acne lesions and repeated treatments with [sic] acne”. Office Action dated September 2, 2011 at page 5. However, in support of the rejection the Examiner states that “while QLT does not exemplify the routine use of repeating acne treatment and subsequently measuring the reduction % of acne lesions, this deficiency is corrected by Kalka.” *Id.* In this regard, the Examiner asserts that Kalka teaches “**repeated** illumination with blue light at cumulative dose of 325 J/cm² resulted in **marked reduction** of both **acne** and seborrhea.” *Id.* (emphasis in original). The Examiner continues with added reference to Khaiat to bolster the teachings of Kalka. However, Khaiat does not relate in any regard to photodynamic therapy.

Whatever else the cited references may disclose, Kalka does not in fact teach the treatment of acne by topically applying a photosensitizer composition to skin tissue of a subject

in need thereof and exposing the tissue of the subject to light energy, as required by the claims. Rather, Kalka mentions that “lipophilic propionibacteria has been utilized for photodynamic destruction of these micro-organisms for the management of acne vulgaris. Repeated illumination with blue light at cumulative dose of 325 J/cm² resulted in marked reduction of both acne and seborrhea. [. . .] The possible value of topical PDT for benign inflammatory skin disease need further exploration.” Kalka, page 403. Such disclosure does not in fact reference the topical application of a photosensitizer composition to skin tissue of a subject exhibiting symptoms of acne. Rather, it merely references the destruction of lipophilic propionibacteria for management of acne vulgaris via use of blue light, and a resultant reduction in both acne and seborrhea. Kalka then suggests the possible value of PDT for benign inflammatory skin diseases and suggests further exploration.

At a minimum, in order to arrive at the presently claimed invention, one of skill would need to modify the teachings of QLT and Kalka (and Khaiat) so as to specifically provide a method with an intent to treat acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof, exposing the tissue to energy at a wavelength capable of activating the photosensitizer, and repeating until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment. Again, the present claims require such a method, including topical application of a photosensitizer composition to skin tissue of a subject and repeating the treating until the desired reduction in acne lesions has been achieved. The Federal Circuit has directly addressed this issue of claim interpretation, and held that “the claims’ recitation of a patient or a human ‘in need’ gives life and meaning to the preamble’s statement of purpose. [. . .] The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed.” *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (*citations omitted*).

In interpreting a claim directed to a “method of treating macrocytic-megaloblastic anemia in... a human in need thereof,” the Federal Circuit held that the claim preamble is a limiting “statement of intentional purpose.” *Jansen v. Rexall Sundown*, 342 F.3d at 1333. The Court explained that “administering the claimed vitamins in the claimed doses for some purpose other

than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method.” “[T]he combination of folic acid and vitamin B[12] must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.” *Jansen v. Rexall Sundown*, 342 F.3d at 1334.

In accordance with proper claim interpretation, the present claims require a method with an intent to treat acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof, exposing the tissue to energy at a wavelength capable of activating the photosensitizer, and repeating until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment. The mere disclosure in Kalka of destruction of lipophilic prionibacteria for management of acne vulgaris, the passing reference to repeated illumination for reduction in both acne and seborrhea, and the express suggestion of possible value of PDT for benign inflammatory skin diseases and of further exploration is just that --- an invitation for further experimentation with no reasonable expectation of success concerning the specific intent of the presently claimed invention.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. There must also be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Moreover, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning **with some rational underpinning** to support the legal conclusion of obviousness.” *KSR Int’l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added).

As mentioned above, nothing in QLT, Kalka, nor Khaiat teaches or suggests a method with an intent to treat acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof, exposing the tissue to energy at a wavelength capable of activating the photosensitizer, and repeating until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment. Absent a suggestion of such a method, one of skill in the art would simply find no motivation to perform a method as recited in the present claims for the specific intended purpose. Further, there is no motivation to

specifically modify the teaching of Kalka so as to arrive at the specifically claimed methods with any reasonable expectation of success. For at least these reasons, one of skill in the art would not look to modify the teachings of QLT alone or in view of Kalka and Khaiat so as to arrive at the presently claimed invention. Withdrawal of this rejection is therefore respectfully requested.

The dependent claims are believed to be patentable for at least the reasons discussed above. In addition, each of the claims further recites specific parameters with regard to the treatment regimen and composition and are separately patentable for at least these reasons.

Claims 9, 11 and 12 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over QLT, Kalka, Khaiat, and further in view of Clement *et al.* (US Pub. 2004/0166129, hereinafter “Clement”). This rejection is respectfully traversed. While not agreeing with the Examiner’s characterization of the cited prior art, whatever else Clement may disclose, it does nothing to remedy the deficiencies of QLT, Kalka and Khaiat discussed above. As such, the cited prior art, taken alone or together, does not teach or suggest the present claims. Withdrawal of this rejection is therefore respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (303) 863-2303 should any additional information be necessary for allowance.

Respectfully submitted,

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